IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

Applicant	: Jeff Korn	Art Unit	: 3737
Serial No.	: 10/615,279	Examiner	: Baisakhi Roy
Filed	: July 8, 2003	Conf. No.	: 8225
Title	: OPTICAL COUPLER FOR ROTATING CATHETER		

Mail Stop Appeal Brief - Patents
Commissioner for Patents
P.O. Box 1450
Alexandria, VA 22313-1450

BRIEF ON APPEAL

(1) Real Party in Interest

The real party in interest is InfraReDx, Inc., a corporation of Massachusetts having a place of business at 34 Third Avenue, Burlington, MA as evidenced by an assignment executed November 12, 2003 and recorded at the U.S. Patent Office on November 17, 2003 at Reel 014697, Frame 0978.

(2) Related Appeals and Interferences

There are no related appeals or interference.

(3) Status of Claims

Claims 1-16 are pending and on appeal. Of these, claims 1 and 10 are independent.

(4) Status of Amendments

All amendments have been entered.

(5) Summary of Claimed Subject Matter

Claim 1

Claim 1's limitation of a housing with a rotatable distal face and a stationary proximal face is introduced on page 5, lines 13-16 of the specification. These structures are also seen FIG. 3, which shows a housing **42** with proximal face **44** and distal face **46**.

The eccentric port **52** and central port **54** are disclosed on page 5, lines 17-25 of the specification. These structures are also seen in FIG. 3.

An embodiment of claim 1's "lens disposed inside the housing" is the R/S lens **92** shown in FIG. 3 and described on page 6, lines 21-25 of the specification. As shown in FIG. 3, the R/S lens **92** intercepts a rotating collection beam **68** that passes through the eccentric port **54**. This is described on page 6, lines 21-25 of the specification. The redirection of the beam by the R/S lens **92** to "a focus proximal to the lens as the collection beam rotates" can clearly be seen in FIG. 5, with the rotation being apparent from the difference between FIGS. 3 and 5.

An embodiment of a "beam re-director" is shown in FIGS. 7 and 8 and described as "centrally mounted beam redirector **51**" on page 6, lines 17-21 of the specification. The delivery beam **58** is shown originating at a light source **32** and redirected by the re-director **51** towards the central port **52**. This too is described on page 6, lines 17-21 of the specification.

Claim 10

Claim 10's limitation of a "rotating catheter" is met by the disclosure, on page 4, lines 16-19 of the specification, of a catheter **16** that includes a jacket **17** surrounding a rotatable core **19**. The same passage discloses a delivery fiber **18** and a collection fiber **20** that extends through the core of the catheter.

Claim 10's limitation of a housing with a rotatable distal face and a stationary proximal face is introduced on page 5, lines 1-3 of the specification. These structures are also seen in FIG. 3, which shows a housing **42** with a proximal face **44** and a distal face **46**.

The eccentric port **52** and central port **54** are disclosed on page 5, lines 17-25 of the specification. These structures are also seen in FIG. 3.

An embodiment of claim 10's "lens disposed inside the housing" is the R/S lens **92** in FIG. 3 and described on page 6, lines 21-25 of the specification. As shown in FIG. 3, the R/S lens **92** intercepts a rotating collection beam **68** that passes through the eccentric port **54**. This is described on page 6, lines 21-25 of the specification. The redirection of the beam by the R/S lens

92 to "a focus proximal to the lens as the collection beam rotates" can clearly be seen in FIG. 5, with the rotation being apparent from the difference between FIGS. 3 and 5.

An embodiment of a "beam re-director" is shown in FIGS. 7 and 8 and described as "centrally mounted beam redirector **51**' on page 6, lines 17-21 of the specification. The delivery beam **58** is shown originating at a light source **32** and redirected by the re-director **51** towards the central port **52**. This too is described on page 6, lines 17-21 of the specification.

(6) Grounds of Rejection to be Reviewed on Appeal

1. The Examiner rejects claims 1-16 as being rendered obvious under 35 USC 103(a) by *Tearney et al.*, U.S. Patent No. 6,134,003.
2. Under the doctrine of obviousness-type double-patenting, the Examiner rejects claims 1-16 as having claims that are obvious variants of those in *Zuluaga et al.*, U.S. Patent No. 6,895,137.

(7) Argument

***Tearney* lacks a housing with a rotatable distal face**

In rejecting claim 1, the Examiner has made the following associations between elements of claim 1 and *Tearney*'s disclosed structure:

Claim Element	Corresponding Structure
"housing"	housing **42** in FIG. 6[1]
"rotatable distal face"	distal end **47** of housing **42**[2]
"stationary proximal face"	proximal end **45** of housing **42**[3]
"central port"	window **60** in housing **42**[4]
"eccentric port"	not present[5]

[1] *Office Action*, page **4**, "*Tearney* et al. discloses an endoscopic unit **34** including a hollow housing **42** having a proximal end **45** and a distal end **47**..."
[2] *Office Action*, page **4**, "*Tearney* et al. discloses an endoscopic unit **34** including a hollow housing **42** having a proximal end **45** and a distal end **47**..."
[3] *Office Action*, page 4, "*Tearney* et al. discloses an endoscopic unit **34** including a hollow housing **42** having a proximal end **45** and a distal end **47**..."
[4] *Office Action*, page 5, "The unit may include a beam director **58**...to direct delivery beam towards the transparent window **60** or central port on to the structure."
[5] *Office Action*, pages 4-5, "Even though *Tearney* et al. do not explicitly mention an eccentric port..."

SECTION 103(a) REJECTION OF CLAIMS 1-16 BASED ON *TEARNEY*

Tearney discloses rotating structures *inside* a housing. The housing, however, does not itself rotate. As a result, the distal end **47** of *Tearney*'s housing **42** is not a "rotatable distal face."

Tearney discloses a device in which "[t]he rotational scanning mechanism **35** imparts movement on either the optical fiber **44**...or a component of the optical system **54**."[6] Neither the fiber **44** nor optical system **54** are part of *Tearney*'s housing **42**. Thus, contrary to the Examiner's position, the distal end **47** of housing **42** in *Tearney*'s FIG. 6 is *not* a rotatable distal face.

In fact, one of ordinary skill in the art would have recognized the danger associated with allowing any portion of housing **42** to rotate. The housing **42**, after all, is intended to be inserted into a blood vessel of a living patient. One of ordinary skill in the art would have recognized that placing a spinning housing **42** in intimate contact with blood in a blood vessel might cause difficulties with a patient's blood circulation.

According to *Tearney*'s FIG. 8, shown below, in one embodiment the motor **74** rotates the fiber, not the housing that encloses it.

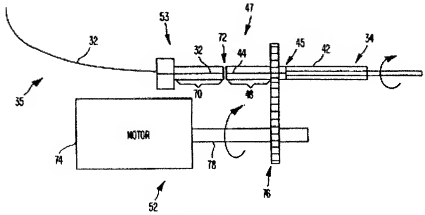


FIG. 8

[6] *Tearney*, col. 7, lines 61-64.

In another embodiment, shown in FIG. 10 below, the motor rotates a mirror **158**. Once again, the housing, which encloses the mirror, remains stationary.

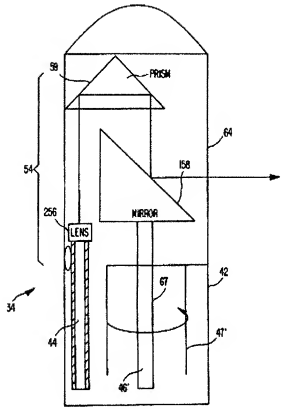
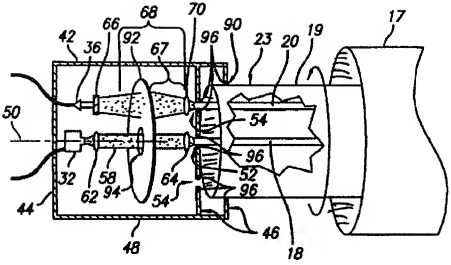


FIG. 10

Thus, although *Tearney* discloses numerous rotating structures, those structures are *inside* the housing. In all cases, the housing itself, including the distal face, remains stationary. This is a sensible approach because it avoids stirring up the blood.

In contrast to *Tearney*'s housing **42**, Applicant's housing is *not* intended for in vivo use at all. The distal face of Applicant's housing, and in fact Applicant's entire optical coupler, lies *outside* the catheter, as shown below in Applicant's FIG. 3. Hence, the dangers associated with having a rotating structure exposed to blood in a blood vessel would not arise.



The structure shown in *Tearney*'s FIG. 6 is not an optical coupler. *Tearney*'s optical coupler is actually the structure labeled **53** shown in FIG. 8 below.

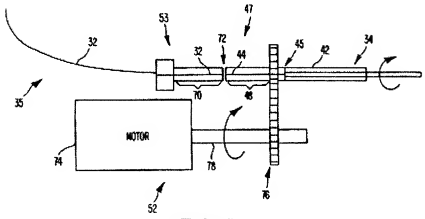
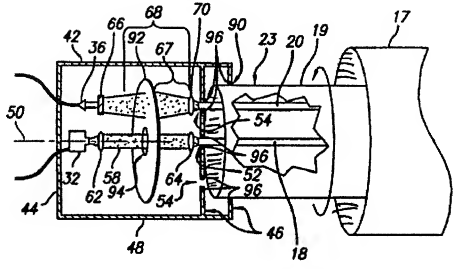


FIG. 8

One of ordinary skill in the art would have noted that since *Tearney*'s optical coupler **53** (see FIG. 8 above) couples from fiber **32** into a centrally disposed fiber **44**, there would be no need for it to have any rotating structure.

Tearney's optical coupler **53** is fundamentally different from Applicant's optical coupler. Applicant's coupler couples light into *two* fibers. In contrast, *Tearney*'s optical coupler couples only into a single fiber.

Referring to Applicant's FIG. 3 below, a first fiber **18** rotates about its own axis, just like *Tearney*'s fiber **44**. A second fiber **20** orbits around the first fiber **18**. Thus, unlike *Tearney*'s optical coupler **53**, which only couples light into a single central fiber, Applicant's optical coupler couples light into two fibers, one of which orbits, or revolves, around the other.



This distinction is reflected in the claim, which recites *two* ports, one for each of *two* fibers: a central port and an eccentric port. The central port couples into the first fiber **18**. The eccentric port couples into the orbiting second fiber **20**. Because the orbiting fiber **20** moves, the eccentric port must also move to keep up with it. Since the eccentric port is in the distal face of the housing, Applicant's housing has a "rotatable distal face."

One of ordinary skill in the art would have realized, upon inspecting *Tearney*'s FIG. 8, that the coupler **53** couples light from fiber **32**, through a port, and into fiber **41**. One of ordinary skill in the art would also have seen that in the device shown in *Tearney*'s FIG. 8, there was no second fiber to couple light into. Accordingly, one of ordinary skill in the art would have had no

plausible basis for modifying *Tearney*'s optical coupler **53** to include any second port, whether eccentric or otherwise.

***Tearney* lacks a lens that intercepts a rotating collection beam**

The Examiner evidently regards lens **56** in *Tearney*'s FIG. 6 as corresponding to claim 1's limitation of:

> "a lens disposed inside the housing to intercept a rotating collection beam emerging from the eccentric port and to re-direct the collection beam to a focus proximal to the lens as the collection beam rotates"

Tearney's lens **56** is not disposed to intercept any rotating beam. In fact, any beam that passes through lens **56** is completely stationary.

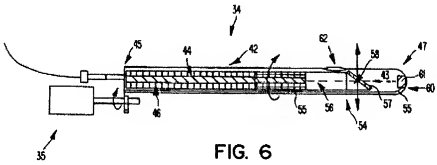


FIG. 6

***Tearney* lacks a beam re-director that directs a beam toward a central port**

Claim 1 recites:

> "a beam re-director disposed between the lens and the distal face, the beam re-director being oriented to direct a delivery beam toward the central port"

The Examiner regards redirector **58** in *Tearney*'s FIG. 6 as meeting this claim limitation.

As shown in the above figure, *Tearney*'s redirector **58** is oriented to direct a beam towards the *side* of the endoscope, away from anything that could be regarded as a "central port." Thus, *Tearney* fails to disclose a beam redirector oriented to direct a beam toward a central port. Instead, *Tearney*'s FIG. 6 discloses the exact opposite: a beam redirector **58** that directs a beam *away* from a central port.

Motivation to modify *Tearney* is flawed

The Examiner concedes *Tearney*'s failure to disclose claim 1's "eccentric port." Nevertheless, the Examiner suggests that one of ordinary skill in the art would have found it obvious to modify *Tearney* to include an eccentric port because:

> "the reference teaches that the coupling member **70** enable [sic] the lenses to couple the rotating beam from a portion of the catheter via the optical connector **48** and focus the beam perpendicularly to axis of rotation of the distal end of the unit. The unit may include a beam director **58** such as a prism or mirror disposed between the lens and the distal face such to direct delivery beam towards the transparent window **60** or central port onto the structure (col. 10 lines 4-1 7, col. 11 lines 1-24)."

It is unclear just how the foregoing reasoning would have led one of ordinary skill in the art to modify *Tearney*'s endoscope to include anything, let alone an eccentric port as required by the claim.

According to *KSR v. Teleflex*, "rejections on obviousness grounds cannot be sustained by mere conclusory statements; instead there must be some articulated reasoning with a rational underpinning to support the legal conclusion of obviousness."[7]

The Examiner's recitation of certain structural elements from *Tearney* and their respective functions hardly seems relevant to eccentric ports. Accordingly, it does not rise to the level of "articulated reasoning with a rational underpinning" as required by *KSR*.

SECTION 103 REJECTION OF CLAIM 10

Claim 10 includes all the limitations of claim 1. Accordingly, Applicant re-asserts all the arguments set forth above in connection with claim 1.

In addition, claim 10 recites the additional limitation that *both* "a collection fiber *and* a delivery fiber" extend through a rotating catheter.

The Examiner has not identified any structure in *Tearney* that includes *two* fibers extending through a rotating catheter. Specifically, claim 10 requires "a rotating catheter having a collection fiber and a delivery fiber extending therethrough."

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[7] *KSR v. Teleflex*, 127 S.Ct. 1727, 1742 (2007).

The Examiner has drawn attention to *Tearney*'s FIG. 6, which is pasted below.

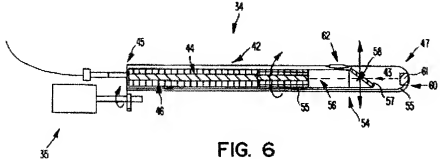

FIG. 6

In FIG. 6, *Tearney* shows a structure that has only *one* fiber extending through a catheter. This structure is not the same as that recited by claim 10. Claim 10 requires *two* fibers, not one. FIG. 6 only discloses *one* fiber, not *two*.

Thus, *Tearney* cannot possibly teach the claim limitation of "a rotating catheter having a collection fiber *and* a delivery fiber extending therethrough." Instead, *Tearney* discloses catheters that have only a *single* fiber.

SECTION 103 REJECTION OF CLAIMS 2 AND 11

Claim 2 recites "a light source disposed to direct a delivery beam radially inward to the beam redirector." The Office draws attention to *Tearney*'s col. 5, lines 1-30 as teaching such a light source.

The text that allegedly teaches claim 2's additional limitation reads as follows:

Optical Sources

Considering each component in more detail, the optical source 2 has characteristics such as wavelength, power, coherence length, and autocorrelation function which are important factors in system performance. In some applications, near infrared sources (1.0–2.0 um) tend to penetrate deeper into many biological media than visible wavelengths and are therefore preferable. The optical radiation source 2 can include in various embodiments: semiconductor sources (light emitting diodes (LED), edge emitting diodes (ELED), superluminscent diodes (SLD), mode-lock lasers (e.g. $Ti:Al_2O_3$, $Cr:Mg_2SiO_4$, $Cr:LiSrAlF_6$), rare earth doped fibers (REDF) (Yb, Nd, Er, Pr, Tm), and supercontinuum or Raman sources. For REDF in order to obtain a good coherence length and autocorrelation function, it may be necessary to insert short period Bragg gratings or long period Bragg gratings into the fiber or use filters external to the fiber to shape the Amplified Spontaneous Emission spectrum (ASE). LED and ELED devices are very-low cost broad bandwidth devices having coherence lengths less than 10 μm. Their main limitation is that typically they have very low power (<100 μW) when coupled into a single spatial mode. SLDs typically have a short coherence length of about ~10 μm, and power of about ~2 μW. Actively and passively mode-locked lasers offer very high power (>100 mW) and short coherence length (<5 μm). Additionally, source powers in excess of 100 mW and coherence lengths under 10 μm can be used. Spectrally shaped REDF, particularly cladding pumped fibers offer good performance in many applications.

In the foregoing passage, *Tearney* merely lists available light sources. It is completely silent on how those light sources are placed. In particular, it says nothing at all about whether those light sources are "disposed to direct a delivery beam radially inward to the beam redirector" (i.e., *Tearney*'s redirector **58**). There is no disclosure in *Tearney* of anything like Applicant's FIG. 8, which shows laser **32** directing a beam radially inward towards redirector **51**.

Claim 11 includes limitations similar to claim 2 and is patentable for at least the same reasons.

SECTION 103 REJECTION OF CLAIMS 3 AND 12

Claims 3 and 12 both require that the beam re-director comprise "a penta-prism."

The Examiner's brief remarks on pages 4-5 of the Office Action fail to identify any "penta-prism" in *Tearney*. Since the Examiner has not made a prima facie obviousness rejection of claim 3, the section 103 rejection of claims 3 and 12 is improper.

Moreover, the rejection fails to comply with 35 USC §132(a), which requires the Examiner, acting on the Director's behalf, to state the reasons for rejection "with such information and references as may be useful in judging the propriety of continuing the prosecution."

SECTION 103 REJECTION OF CLAIMS 6 AND 15

Claims 6 and 15 both recite the additional limitation of "a detector disposed at the focus for receiving the rotating collection beam."

The Examiner's brief remarks make no attempt to identify where *Tearney* teaches or suggests the claimed detector. Accordingly, the Examiner has failed to make a prima facie obviousness rejection of claims 6 and 15. The section 103 rejection of claims 6 and 15 is thus flawed and should be reversed.

Moreover, the rejection fails to comply with 35 USC §132(a), which requires the Examiner, acting on the Director's behalf, to state the reasons for rejection "with such information and references as may be useful in judging the propriety of continuing the prosecution."

SECTION 103 REJECTION OF CLAIM 8

Claim 8 recites the additional limitation of a lens that is "configured to focus the collection beam off an axis of rotation of the distal face."

The Examiner has said nothing at all about where *Tearney* teaches or suggests the additional limitation of claim 8. Nor is it readily apparent where these limitations are taught. Accordingly, the section 103 rejection of claim 8 is incomplete.

Moreover, the rejection fails to comply with 35 USC §132(a), which requires the Examiner, acting on the Director's behalf, to state the reasons for rejection "with such information and references as may be useful in judging the propriety of continuing the prosecution."

SECTION 103 REJECTION OF CLAIMS 9 AND 16

Claims 9 and 16 recite the limitation of a lens that comprises an "axicon lens."

The Examiner's brief remarks do not identify any teaching or suggestion of an axicon lens in *Tearney*. Therefore, the section 103 rejection of claims 9 and 16 is improper.

Moreover, the rejection fails to comply with 35 USC §132(a), which requires the Examiner, acting on the Director's behalf, to state the reasons for rejection "with such information and references as may be useful in judging the propriety of continuing the prosecution."

DOUBLE PATENTING REJECTION

An obviousness-type double-patenting rejection of a claim is appropriate when that claim is an obvious variant of a claim in an issued patent or pending application. Thus, in an obviousness-type double patenting rejection, the two claims must purport to cover obvious variants of the same subject matter.

The Examiner's remarks suggest a misunderstanding in the concept of double-patenting. A double-patenting rejection is only proper when two claims recite the same, or essentially the same, subject matter. The fact that one claim dominates another is, by itself, insufficient to support a double-patenting rejection. In recognition of the confusion between domination and double-patenting, the MPEP advises Examiners that

> "[D]omination and double patenting should not be confused. They are two separate issues. One patent or application "dominates" a second patent or application when the first patent or application has a broad or generic claim which fully encompasses or reads on an invention defined in a narrower or more specific claim in another patent or application. Domination by itself, i.e. in the absence of statutory or non-statutory double patenting grounds, cannot support a double patenting rejection."[8]

The Examiner states that certain claims in U.S. Patent No. 6,895,137 "anticipate the claims in the current application."[9] The Examiner then states that "[t]he patented claims include

[8] MPEP 804(II).
[9] *Office Action*, page 3.

additional structural limitations of the optical coupler system"[10] and that these patented claims are "more specific than the current application claims."[11]

However, as discussed in the above section from the MPEP, whether one claim "anticipates" or "dominates" another is irrelevant to double-patenting. A double-patenting rejection requires that two claims recite obvious variants of the *same* subject matter.[12]

US 6,895,137

All the claims of *Zuluaga* et al., U.S. Patent No. 6,895,137 lack the limitation of a housing having a stationary proximal face and an eccentric port in a distal face thereof. These claims are therefore all different from at least claim 1 of the '137 patent. The Examiner does not provide reasoning for why one of ordinary skill in the art would have found this difference obvious. Accordingly, the double-patenting rejection based on the '137 patent is improper.

Double Patenting Rejection Based on 10/309,477

The claims stand provisionally rejected on the ground of obviousness-type double patenting over the claims in co-pending parent application Serial No. 10/309,477.

Per MPEP § 804.I.B.1., "[i]f the ODP rejection is the only rejection remaining in the later-filed application, while the earlier application is rejectable on other grounds, a terminal disclaimer must be filed in the later-filed application before the rejection can be withdrawn."

The 10/309,477 application is still actively in prosecution, making the scope of the claims indeterminate at the present time. Accordingly, Applicant proposes that this rejection be held in abeyance until the conditions set forth in MPEP 804.I.B.I are met.

(8) Conclusion

The brief fee of $255 was paid with the Appeal Brief filed on April 16, 2008. Please apply the difference between the fees due ($270) and the fees already paid ($255), totaling $15,

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[10] *Id.*
[11] *Id.*
[12] See *Ortho Pharmaceutical v. Smith*, 959 F.2d 936, 22 USPQ 2d 1119 (Fed. Cir. 1992). "It is the claims, not the specification, that define an invention... And it is the claims that are compared when assessing double patenting."

along with any other charges or credits to Deposit Account No. 06-1050, referencing Attorney Docket No. 12258-036001.

Respectfully submitted,

Date: 3/24/09

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Appendix of Claims

1. An optical coupler comprising:

a housing with a rotatable distal face and a stationary proximal face, the distal face having an eccentric port and a central port;

a lens disposed inside the housing to intercept a rotating collection beam emerging from the eccentric port and to re-direct the collection beam to a focus proximal to the lens as the collection beam rotates; and

a beam re-director disposed between the lens and the distal face, the beam re-director being oriented to direct a delivery beam toward the central port.

2. The optical coupler of claim **1**, further comprising a light source disposed to direct a delivery beam radially inward to the beam re-director.

3. The optical coupler of claim **1**, wherein the beam re-director comprises a penta-prism.

4. The optical coupler of claim **1**, wherein the beam re-director comprises a prism.

5. The optical coupler of claim **1**, wherein the beam re-director comprises a mirror.

6. The optical coupler of claim **1**, further comprising a detector disposed at the focus for receiving the rotating collection beam.

7. The optical coupler of claim **1**, wherein the lens is configured to focus the collection beam on an axis of rotation of the distal face.

8. The optical coupler of claim 1, wherein the lens is configured to focus the collection beam off an axis of rotation of the distal face.

9. The optical coupler of claim 1, wherein the lens comprises an axicon lens.

10. A system for identifying vulnerable plaque, the system comprising:

a rotating catheter having a collection fiber and a delivery fiber extending therethrough;

a housing with a rotatable distal face and a stationary proximal face, the distal face having an eccentric port and a central port;

a lens disposed inside the housing to intercept a rotating collection beam emerging from the eccentric port and to re-direct the collection beam to a focus proximal to the lens as the collection beam rotates; and

a beam re-director disposed between the lens and the distal face, the beam re-director being oriented to direct a delivery beam toward the central port.

11. The system of claim 10, further comprising a light source disposed to direct a delivery beam radially inward to the beam re-director.

12. The system of claim 10, wherein the beam re-director comprises a penta-prism.

13. The system of claim 10, wherein the beam re-director comprises a prism.

14. The system of claim 10, wherein the beam re-director comprises a mirror.

15. The system of claim **10**, further comprising a detector disposed at the focus for receiving the rotating collection beam.

16. The system of claim **10**, wherein the lens comprises an axicon lens.

Evidence Appendix

None.

Related Proceedings Appendix

None.